DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 10, 2014

MicroVention, Inc.
Ms. Naomi Gong
Sr. Regulatory Affairs Project Manager
1311 Valencia Ave
Tustin, California 92780

Re: K142014
Trade/Device Name: SOFIA Distal Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DQO
Dated: September 9, 2014
Received: September 10, 2014

Dear Ms. Naomi Gong,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K142014

Device Name
SOFIA Distal Access Catheter

Indications for Use *(Describe)*
The SOFIA Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

| | |
|---|---|
| **Trade Name:** | SOFIA Distal Access Catheter |
| **Generic Name:** | Percutaneous Catheter |
| **Classification:** | Class II, 21 CFR 870.1250 (DQY), 21CFR 870.1200 (DQO) |
| **Submitted By:** | MicroVention, Inc<br>1311 Valencia Avenue<br>Tustin, California U.S.A. |
| **Contact:** | Naomi Gong<br>Phone #: 714-247-8055 |
| **Date:** | 2014 September 30 |
| **Predicate Device:** | SOFIA Distal Access Catheter (K131482) |

**Device Description:**

The SOFIA™ Distal Access Catheter is a single-lumen, flexible catheter designed with coil and braid reinforcement. The distal segment is steam-shapeable and it has a hydrophilic coating for navigation through the vasculature. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy. An introducer sheath and shaping mandrel are also provided.

**Indications For Use:**

The SOFIA™ Distal Access Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.

**Technological Comparison**:

| | **SOFIA Distal Access Catheter** (predicate) | **SOFIA Distal Access Catheter** (proposed) |
|---|---|---|
| Intended Use | Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries. | Same |
| Material<br>Catheter Body<br><br><br><br><br>Marker<br>Hub<br>Strain Relief<br>Introducer<br>Shaping Mandrel | <br>Outer layer of polyurethane elastomer (Polyblend and Pellethane), polyether block amide (Pebax) and polyamide (Grilamid); inner layer of stainless steel braid/coil, PTFE and polyolefin elastomer<br><br>Platinum/Iridium<br>Nylon<br>Polyurethane<br>Pebax<br>Stainless steel | Same |
| Catheter size | 5 F | Same |
| ID | 0.055 inch (1.4 mm) | Same |
| OD | 0.068 inch (1.7 mm) | Same |
| Effective Length | 125 cm | 115 cm |

| | **SOFIA Distal Access Catheter** (predicate) | **SOFIA Distal Access Catheter** (proposed) |
|---|---|---|
| Coating | Hydrophilic coating (Hydak®) | Same |
| Tip Configuration | Steam shapeable by user | Same |
| Guidewire Compatibility | 0.035 inch or 0.038 inch | Same |
| Accessories | Introducer sheath and shaping mandrel | Same |
| Method of Supply | Sterile and single use | Same |
| Sterilization Method | Ethylene Oxide | Same |
| Packaging Configuration | Catheter placed into a HDPE dispenser tube. Dispenser tube, introducer and shaping mandrel placed on a polyethylene packaging card that is inserted into a Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box. | Same |

## Verification and Test Summary:

| **Bench Testing** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Simulated Use | Test articles achieved a rating $\geq 3$ for preparation/ease of assembly, introducer sheath interaction, introducer peel away, tracking with guidewire/microcatheter, microcatheter/guidewire lockup, lubricity and durability of hydrophilic coating, microcatheter/ guidewire removal.<br><br>Removal/ aspiration of clot, mechanical clot retriever and stent delivery with no particles.<br>(Prior test data from predicate device) | Device performs as intended under simulated use conditions |
| Equipment Interface | Test articles compatible with 0.035-inch and 0.038-inch guidewires, 6F or larger guide catheter/guiding sheath, common RHVs using insertion tool, stopcocks and $\leq$ 0.027-inch microcatheters<br>(Prior test data from predicate device) | Device compatible with recommended accessories commonly used in intravascular procedures |
| Dimensional and Physical Attributes | Test articles met the specified dimensional requirements for catheter OD, catheter ID, overall working length, length of distal section, length of distal tip to marker band and total length of hub/strain relief | Device met established dimensional and physical specifications |
| Kink Resistance | No kinks at 1 cm, 4 cm, 12 cm and 25 cm from distal tip when wrapped around 0.025-inch and 0.030-inch pin gauges<br><br>No kinks noted during simulated use testing<br>(Prior test data from predicate device) | Device resistant to kinking around small radii turns |
| Tip Shapeability | Tip angle of test article equivalent to competitive devices after steam shaping using mandrel with an angle of approximately $90^{o}$<br>(Prior test data from predicate device) | Shapeability of distal tip after steam shaping equivalent to competitive devices |
| Radio Detectability | Distal marker band visible under fluoroscopy<br>(Prior test data from predicate device) | Device radiopacity equivalent to or better than predicate and competitive devices |

| **Bench Testing** | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Gauging (ISO 594-2) | Gauging pin and hub align in limit planes<br>(Prior test data from predicate device) | Device hub meets the requirements of ISO 594-2 |
| Separation Force (ISO 594-2) | Mating parts separation force greater than 25 N<br>(Prior test data from predicate device) | Device hub meets the requirements of ISO 594-2 |
| Unscrewing Torque (ISO 594-2) | Test article luer remains attached after applying an unscrewing torque not less than 0.02 Nm for a minimum of 10 seconds<br>(Prior test data from predicate device) | Device hub meets the requirements of ISO 594-2 |
| Stress Cracking (ISO 594-2) | No stress cracks on test article hub<br>(Prior test data from predicate device) | Device hub meets the requirements of ISO 594-2 |
| Ease of Assembly (ISO 594-2) | Components fit together securely with no resistance observed between test article luer and reference fitting<br>(Prior test data from predicate device) | Device hub meets the requirements of ISO 594-2 |
| Resistance to Overriding (ISO 594-2) | Test article luer does not override reference fitting threads<br>(Prior test data from predicate device) | Device hub meets the requirements of ISO 594-2 |
| Durability/Lubricity of Hydrophilic Coating | Test article achieved a rating of $\geq$ 3 during simulated use testing for coating durability and lubricity. | Device tracks easily with no coating cracking or separation |
| Catheter Stiffness | Device stiffness equivalent to predicate and competitive devices<br>(Prior test data from predicate device) | Device tracks in tortuous anatomy while advancing to target site |
| Torque Strength | No catheter breakage after 50 rotations<br>(Prior test data from predicate device) | Device torque strength same as predicate device |
| Catheter Flexural Fatigue | No flexural fatigue following repeated bending during simulated use testing and repeated hoop stress following pressure and air aspiration testing<br>(Prior test data from predicate device) | Device integrity suitable for intended clinical use |
| Surface Contamination | Test article free from surface contaminants from uncured coating surface particulates > 0.02 $mm^2$, embedded particulates<br><br>Distal tip smooth and tapered<br><br>PTFE inner layer not delaminated | Device integrity suitable for intended clinical use |
| Force at Break (Distal and Hub) | Catheter force at break $\geq$2.25lbf for distal section and hub/catheter junction<br>(Prior test data from predicate device) | Tensile strength test results equivalent to predicate and competitive devices |
| Flow Rate | Flow rate at 100 psi and 300 psi with diagnostic agents (e.g., saline, contrast media) equivalent to predicate device | Device meets specified requirements for delivery of diagnostic agents |
| Static Burst Pressure | No damage of pressurized catheter at 46 psi<br>(Prior test data from predicate device) | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Fluid Leakage at > 46 psi | No liquid leakage from hub and catheter shaft at 46 psi for 30 seconds<br>(Prior test data from predicate device) | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Air Leakage | No air leakage at hub into syringe for 15 seconds<br>(Prior test data from predicate device) | Device integrity suitable for intended clinical use and met requirements of ISO 10555-1 |
| Dynamic Burst | Test articles did not burst at or below 300 psi<br>(Prior test data from predicate device) | Device met labeled maximum infusion pressure of 300 psi |
| Particulate Test | Less than 25 particles greater than 10 microns per ml volume and less than 3 particles greater than 25 microns per ml volume<br>No particles greater than 70 microns<br>(Prior test data from predicate device) | Device met specifications for maximum allowable particles |

Note: Biocompatibility was prior test data from predicate device.

| Biocompatibility | Result | Conclusions |
|---|---|---|
| Cytotoxcitiy (ISO 10993-5)<br>- MEM elution assay | Cell culture treated with test article exhibited slight reactivity (Grade 1) | Non-cytotoxic |
| Sensitization/Irritation (ISO 10993-10)<br>- Guinea pig maximization sensitization | Extracts of the test article elicited no reaction at the challenge (0% sensitization) following the induction phase (Grade 1). | Weak allergic potential or sensitizing capacity |
| Sensitization/Irritation (ISO 10993-10)<br>- Intracutaneous reactivity | Extracts of the test article did not show a significantly greater biological reaction than the sites injected with the control article | Non-irritant |
| Hemocompatibility – Rabbit Blood Direct and Indirect Contact (ISO 10993-4) | The hemolysis index was 0.13% (direct contact) and 0.0% (indirect contact) | Non-hemolytic |
| Hemocompatibility – Unactivated Partial Thromboplastin Time Assay Direct Contact (ISO 10993-4) | No statistically significant difference found between the Unactivated Partial Thromboplastin Time (UPTT) of the plasma exposed to the test article and that of the plasma exposed to either the negative control or the untreated control | No effect on coagulation |
| Hemocompatibility – Complement Activation Assay (ISO 10993-4) | C3a and SC5b-9 levels $\leq$ negative and untreated controls | No effect on complement activation |
| Hemocompatibility – Thrombogenicity Study in Dogs (ISO 10993-4) | Minimal thrombosis observed with a Grade 0 in two out of two test sites and two out of two control sites | No significant thrombosis |
| Systemic Toxicity – Systemic Injection Test (ISO 10993-11) | Extracts of test article did not induce a significantly greater biological reaction than the control extracts when injected in Swiss Albino mice | No toxic effects |
| Systemic Toxicity - Rabbit Pyrogen Test (ISO 10993-11) | The temperature increases (maximum) was 0.03$^{o}$C from baseline | Non-pyrogenic |

**Summary of Substantial Equivalence:**

The data presented in this submission demonstrates the technological similarity and equivalency of the SOFIA Distal Access Catheter when compared with the predicate device, SOFIA Distal Access Catheter (K131482).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Are packaged and sterilized using same methods.

In summary, the SOFIA Distal Access Catheter described in this submission is substantially equivalent to the predicate device.